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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,844	03/29/2006	Giovanni Giuliani	BA-22970 PCT	4329
178 7590 08/18/2009 BUCKNAM AND ARCHER 1077 NORTHERN BOULEVARD ROSLYN, NY 11576				
EXAMINER LEE, BENJAMIN HYOUNGSOOL				
ART UNIT		PAPER NUMBER		
3739				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/573,844

Applicant(s)

GIULIANI ET AL.

Examiner

BENJAMIN LEE

Art Unit

3739

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-14 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-10, 13-14 is/are rejected.
7) ☒ Claim(s) 1 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SF-08)
Paper No(s)/Mail Date 3/29/06
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Claim Objections

1. **Claim 1** is objected to because of the following informalities: "80,000" should be amended to --80,000--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The means suitable for the identification of the coronary vessel to be treated are indefinite because it is unclear whether the thoracic support alone or in combination with other elements constitutes the means. It is clear that the thoracic support is included in the means, however the language following "thoracic support" is considered to be functional language.

Claim 3 recites the limitation "the command and drive means" in line 1. There is insufficient antecedent basis for this limitation in the claim. The phrase "the command and drive means" should be amended to --the control and drive means--.

Claim Rejections - 35 USC § 102

3. **Claims 1-2, 5-10, and 13-14** are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Canali (USPN 6,397,103).

As to claim 1, Canali teaches an apparatus (Figs. 1 & 2) for the emission of a combined flux of electrons and electromagnetic radiations capable of being used for the treatment of the atheromatous disease, since the apparatus is useful for arterial and venous vascular diseases (col. 3, lines 32-35), comprising:

- two electric circuits (2,2') with opposed polarity, a circuit with positive polarity and the other one with negative polarity fed by the same alternate current distribution network (30) each circuit comprising an electric or electronic device (7,7') transforming the alternate current of the distribution network into direct current and supplies a direct current with a voltage comprised between 4,000 and 80,000 V and an intensity comprised between 0.05 and 0.5 mA (col. 3, lines 46-62);
- two outputs (8,8') one of which is connected to the circuit with positive polarity and the other one to the one with negative polarity (col. 3, lines 60-62),
- two plate terminal wires (9,9'), each of them being provided with at least one bundle of pointed wire elements (11,11'), a wire being connected to the output of the circuit with positive polarity and the other wire being connected to the output of the circuit with negative polarity (col. 3, lines 63-65),
- a control and drive means 25 in the form of a warning light controls when the apparatus is in use (col. 4, lines 48-49) and therefore controls the plate

terminal wires. The combined flux of electrons and electromagnetic radiations emitted is capable of being directed in a concentric and accurately targeted way towards the coronary vessel since the components of the device responsible for emitting the flux of electrons and electromagnetic radiations are identical to those disclosed by Canali.

- a bed 13 (col. 4, lines 65-66) suitable for the identification of the coronary vessel corresponding to the stenosis or lesion to be treated since it assists a doctor in identifying the region of interest.

As to claim 2, Canali teaches the means suitable for the identification of the coronary vessel to be treated is constituted by a thoracic support (13) in the form of a bed (col. 4, lines 65-66). On this bed, a doctor is capable of configuring a mapping of the coronary tree obtained by a chest X-ray, performing a coronarography examination, and measuring the vessels to be treated where x-axis and y-axis coordinates set the goniometric measurements.

As to claim 5, Canali teaches the treatment time may be predetermined and regulated by a timer 14 (col. 4, lines 50-51) which is inherently programmable since the treatment time may be predetermined. Furthermore, the timer is placed on at least one of the two electric circuits since the timer 14 is installed into the apparatus 10 (Fig. 1) and the circuits are implemented within the same apparatus (Col. 3, lines 33-35). The timer is capable of being used for the emission of an intermittent flux or at adjustable intervals since the timer is set for predetermined treatment times (col. 4, lines 50-51).

As to claims 6-7, Canali teaches the surface of the cross section of each bundle of pointed wire elements (11, 11') is comprised preferably between 0.1 and 2 mm², and up to 10mm² (col. 4, lines 61-63).

As to claim 8, Canali teaches each bundle (11, 11') is constituted by a number of wire elements comprised between 50 and 10,000 (col. 4, lines 61-64) which encompasses the range between 100 and 10,000.

As to claim 9, Canali teaches each bundle (11, 11') is divided into many groups of pointed wire elements and the groups forming a bundle can be up to 100 in number since the number of bundles on each plate terminal wire may range from 1-100 (col. 4, lines 58-59).

As to claim 10, Canali teaches the pointed wire elements are carbon fibres (col. 3, lines 64-44).

As to claim 13, the apparatus is capable of being used in the treatment and/or prevention of the atheromatous disease, wherein the stenosis is not higher than 75%, since the apparatus is useful for arterial and venous vascular diseases (col. 3, lines 32-35). The apparatus is capable of orienting the two bundles of pointed wire elements (11, 11') in a targeted and concentrated way towards the part of the body corresponding to the stenosis or lesion to be treated since the components of the device responsible for emitting the flux of electrons and electromagnetic radiations are identical to those disclosed by Canali. The part of the body is also insulated from ground since the apparatus includes the insulating bed 13 (col. 4, lines 65-66). The apparatus is capable

of delivering between the bundles (11, 11') a direct current having a voltage comprised between 4,000 and 80,000 V and an intensity comprised between 0.05 and 0.5 mA (col. 3, lines 58-65).

As to claim 14, Canali teaches the apparatus is capable of delivering direct current intermittently since a timer 14 regulates the treatment time.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Canali (USPN 6,397,103), as applied to claim 1 above, in view of Morse (USPN 1,945,327).

As to claim 3, Canali does not expressly teach the command and drive means of the plate terminal wires are light means (40) mounted on the plate terminal wires which are oriented in such a way to light the area to be treated and have a visual control of the area involved with the treatment. However, Morse teaches an electrosurgical apparatus (a combined tongue depressor and electrode) where an electrical bulb is secured thereto in order to illuminate the inside of a patient's mouth so that the doctor will have a well lighted field in which to work (col. 2, lines 75-81). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement the command and drive means of the plate terminal wires as a light mounted on the plate terminal wires since Morse teaches a similar feature that provides the advantage of a well lit field in which to work (col. 2, lines 75-81).

7. **Claim 4** is rejected under 35 U.S.C. 103(a) as being unpatentable over Canali (USPN 6,397,103), as applied to claim 1 above, in view of Logan (USPN 2,590,191), and further in view of Rose et al. (USPN 4,260,258).

As to claim 4, Canali does not expressly teach the control and drive means of the plate terminal wires are LEDS or nano-emitters, at least three in number, which are positioned around the area to be treated. However, Logan teaches an arrangement of light sources to obtain high levels of illumination during surgery (col. 2, lines 3-18). Furthermore, using LEDs would have been an obvious modification since it is well known that LEDs produce very little heat, as taught by Rose (col. 7, lines 49-51). It would have been obvious to one of ordinary skill in the art at the time of the invention implement the control and drive means of the plate terminal wires as at least three LEDS positioned around the area to be treated since Logan teaches the advantages of an arrangement of light sources to obtain high levels of illumination during surgery (col. 2, lines 3-18) and because LEDs produce very little heat (Rose, col. 7, lines 49-51). Note that the claim does not require that the control and drive means are detected from special cameras positioned on the two plate terminal wires.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In regards to claim 4, Chung (USPN 6,426,590) teaches the advantages of nanoemitters as a light source and Wahrburg (WO 0200131) teaches a robotic control system where an instrument sensor includes plural light emitting diodes to generate a position indication of the instrument and an optical detector receives the

sensor signals for monitoring the position of the sensor and determining orientation of the instrument.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN LEE whose telephone number is (571)270-1407. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571)-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Linda C Dvorak/
Supervisory Patent Examiner, Art
Unit 3739

/B. L./ 8/11/09
Examiner, Art Unit 3739